UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	03-CV-1293 (WJM) **OPINION**

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MARTINI, U.S.D.J.:

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") appeal from the May 13, 2005 Order of Magistrate Judge Patty Schwartz denying Teva leave to amend their answers to include an affirmative defense of unenforceability due to inequitable conduct.[1] Magistrate Judge Schwartz held that Teva had not shown good cause for amending the Pretrial Scheduling Order pursuant to Fed. R. Civ. P. 16(b) and, therefore, denied Teva's motion. Judge Schwartz also rendered "observations" that Teva's proposed amendment was unduly delayed, unduly prejudicial to Wyeth, and futile, and thus would likely be denied under Fed. R. Civ. P. 15(a) as well. But, Judge Schwartz did so without affirmatively denying Teva's motion to amend under Rule 15(a). Teva appeals the May 13, 2005 Order, arguing that it is clearly erroneous and contrary to law pursuant to Fed. R. Civ. P. 72(a) and L. Civ. R. 72.1(c)(1)(A).

Background

This is a patent infringement action. Wyeth charges Teva with infringing three of its patents: U.S. Patent Nos. 6,274,171 B1 (the "'171 patent"); 6,419,958 B2 (the "'958 patent"); and 6,403,120 B1 (the "'120 patent"). These patents have substantially identical specifications and are directed to an extended release formulation of venlafaxine hydrochloride. Wyeth listed

[1]Although Teva USA and Teva Ltd. each submitted their own proposed amended answer, the parties refer to them collectively as "Teva," in the singular, for purposes of this appeal because both companies seek to amend their answers to include the same inequitable conduct defense. For the sake of consistency, the Court shall do so as well.

these patents in its Effexor® XR[2] New Drug Application ("NDA") No. 20-699, which is directed to the use of venlafaxine hydrochloride extended release capsules "for the treatment of depression including depression with associated anxiety." (Steiner Decl. Ex. 3 at WYETH 004-000003).

Teva, seeking to market a generic version of Effexor® XR, filed an Abbreviated New Drug Application ("ANDA") for an extended release venlafaxine formulation. As part of the ANDA process, Teva provided Wyeth with notice that Teva's ANDA contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV).[3] Wyeth then brought this action against Teva charging patent infringement on March 27, 2003.

Seven of the independent claims asserted against Teva claim a "method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis . . . ." '171 patent, claims 20, 22, 23; '958 patent, claims 1, 3, 4; '120 patent, claim 1. Support for that claim language is found in the specifications of the patents-in-suit:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. *Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies*.

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[2]"XR" is the abbreviation for extended release.

[3]A Paragraph IV certification must disclose an ANDA applicant's basis for asserting that its generic product will not infringe the patents listed in the NDA, and/or the basis for asserting that the patent claims are invalid.

'171 patent, col. 2, ll. 46-55 (emphasis added).[4] Teva asserts that Wyeth misrepresented its invention to the U.S. Patent and Trademark Office ("PTO") by making the italicized statement above (hereinafter "the statement") without any clinical studies in support thereof, and, as a result, committed inequitable conduct. On February 22, 2005, Teva requested leave to amend its answers to add that affirmative defense of inequitable conduct.

Before addressing the Magistrate Judge's resolution of that motion, it is necessary to go back in time so that Teva's request can be viewed in its proper context. On June 30, 2003, the Court entered a Pretrial Scheduling Order establishing December 31, 2003 as the deadline for amendment of pleadings. The parties engaged in fact discovery and on October 31, 2003, Wyeth produced its NDA. The NDA disclosed all clinical studies concerning Effexor® XR conducted by or for Wyeth. After reviewing the NDA, "it raised a red flag"[5] for Teva that it may have an inequitable conduct claim. However, Teva did not seek to amend its answers before the deadline, nor did it request that the deadline be extended. Teva professes that its inaction was due to its inability to determine whether the clinical studies supported the statement without the benefit of taking additional discovery. (*See* Teva Reply Br. at 7).

By October 4, 2004, Wyeth had substantially completed its document production. Teva then deposed each of the four inventors. Each inventor allegedly "confessed ignorance concerning support for the statement in the patent[s]." (Teva Reply Br. at 4). Teva then noticed a 30(b)(6) deposition. Wyeth produced two 30(b)(6) witnesses in February 2005, and it was at

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[4]Because the patents have substantially identical specifications, the Court cites only to the specification of the '171 patent.

[5](5/9/05 Tr. at 6).

those depositions where Teva allegedly confirmed for the first time which studies Wyeth contends support the statement: 600B-208-US ("the 208 study"), 600B-209-US ("the 209 study"), and 600B-367-EU ("the 367 study"). Further, according to Teva, it was only after taking those 30(b)(6) depositions that it was able to confirm its suspicions that Wyeth had no support for the statement. And thus, Teva filed its motion for leave to amend in February 2005.

On May 9, 2005, at the hearing on Teva's motion, Magistrate Judge Schwartz denied Teva's request, holding that Teva failed to demonstrate good cause to modify the scheduling order under Rule 16. Judge Schwartz reviewed Teva's request under Rule 16 because of the June 30, 2003 Pretrial Scheduling Order, which established the December 31, 2003 deadline for amendment of pleadings. The Magistrate Judge was not persuaded by Teva's protestations that it could not reasonably have sought to amend its answers before the deadline. Rather, Judge Schwartz found that Teva had sufficient information – the NDA and its disclosure of all clinical studies – in October 2003 to assert an inequitable conduct defense based on lack of clinical study support. Judge Schwartz further found Teva's argument that it needed additional discovery to "confirm" the factual underpinnings of its inequitable conduct allegations to be unpersuasive: "Given that the NDA reflected all the studies that related to the XR formulation, there was really no need to wait until the end of fact discovery to investigate the claims it now seeks to lodge." (5/9/05 Tr. at 90).

Teva then appealed that decision. That appeal is now before this Court.

Discussion

A district court may reverse a Magistrate Judge's order if it finds the ruling clearly erroneous or contrary to law. *See* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). The district court is bound by the clearly erroneous rule as to findings of fact, while the phrase "contrary to law" indicates plenary review as to matters of law. *Haines v. Liggett Group Inc.*, 975 F.2d 81, 91 (3d Cir. 1992). According to the Supreme Court, "a finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948).

Rule 16(b) of the Federal Rules of Civil Procedure governs amendment of pleadings once a scheduling order has been entered. *See Eastern Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).[6] Rule 16 provides that a scheduling order "shall not be modified except upon a showing of good cause and by leave of the district judge or, when authorized by local rule, by a magistrate judge." Fed. R. Civ. P. 16(b). Good cause depends on the diligence of the moving party. *Globespanvirata, Inc. v. Texas Instruments Inc.*, 2005 WL 1638136, *3 (D.N.J. Jul. 12, 2005). The moving party must show that despite its diligence, it could not reasonably have met the scheduling order deadline. *S&W Enters., LLC v. Southtrust Bank of Ala., NA*, 315 F.3d 533, 535 (5th Cir. 2003). Further, the absence of prejudice to the nonmovant is not a consideration under the good cause standard. *Globespanvirata, Inc.*, 2005 WL 1638136 at *3.

[6]Because a request to modify a pretrial order is considered to be a procedural issue unrelated to the patent laws, it is reviewed under the law of the regional circuit. *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1262 (Fed. Cir. 2002).

Here, it is uncontested that a Pretrial Scheduling Order was issued on June 30, 2003 and that the Order established December 31, 2003 as the deadline for amendment of the pleadings. Consequently, Teva's motion for leave to amend its answers was properly considered under the Rule 16(b) "good cause" standard.

Teva argues that Judge Schwartz's finding that it was not diligent is clearly erroneous. Teva asserts that it could not have reasonably amended its answers before the December 31, 2003 amendment cutoff. According to Teva, it could not determine from Wyeth's NDA which three studies supported the statement. Teva offers two reasons why the NDA by itself was insufficient. (*See* Teva Reply Br. at 7). First, the NDA is directed to only one indication for Effexor® XR, the treatment of depression. However, other clinical studies, concerning other indications, could have provided support for the statement. Second, the NDA identifies studies other than the 208, 209 and 367 studies which Wyeth may have relied upon when making that statement. Put differently, Teva essentially argues that because the NDA contained more than 3 studies, and Wyeth may have relied on any group of three to make the statement, Teva had insufficient information before the amendment deadline to properly plead an inequitable conduct defense. As a result, Teva asserts that it needed to take additional discovery to determine Wyeth's alleged bases for the statement.

Teva's arguments are factually incorrect and, ultimately, unconvincing. In her thorough analysis stated on the record on May 9, 2005, Judge Schwartz found Teva had not been diligent before the amendment deadline:

> The Court has not been presented with any information as to why there was any confusion about whether the three studies in the NDA were different than those in the patent application . . . . Thus,

> it appears to this Court that there was sufficient information long before February 2005 . . . upon which Teva could have sought leave or at least could have come before this Court and sought an extension at that time. In short, it appears that, at least from October 2003, Teva had possession of the information upon which it now relies for its proposed amendment.

(5/9/05 Tr. at 89, 91). Teva's arguments fail to demonstrate otherwise.

First, the three studies Wyeth relied on in making the statement are easily recognizable. The patent refers to two eight-week and one-twelve week studies. The NDA discloses three completed studies: the 208, 209 and 367 studies. The 208 and 209 studies were eight weeks in length, while the 367 study was twelve weeks in length. Teva argues that it could not have known that these were the three relevant studies because there are two other eight-week and one other twelve-week studies. (Teva Reply Br. at 2 (citing Steiner Decl. Ex. 3 at WYETH 004-000079-81)). However, and Teva should have known this, at the time those studies were reported in the NDA, "[n]o interim data [were] available." (Steiner Decl. Ex. A at WYETH 004-017122, 19080, 17206). Thus, Teva has presented no reasonable explanation why those three studies caused it any confusion when trying to ascertain which studies support the statement.

Teva also argues that it could not have known which studies were relied upon because the NDA includes "[o]ther studies of unidentified length" which were ongoing. (Teva Reply Br. at 3 (citing Steiner Decl. Ex. 3 at WYETH 004-000077-78)). Those other studies, Teva posits, could have been eight or twelve weeks in duration and, therefore, they potentially could have been support for the statement. However, an examination of the pages cited by Teva reveals that the duration of those studies was "6-12 mos". (*Id.*). Not surprisingly, Teva fails to explain why it confused those two studies with the 208, 209 and 367 studies.

In short, none of the five additional studies that allegedly caused Teva confusion could have been relied upon by Wyeth to show a statistically significant improvement. Further, Teva does not identify any other study that could have been confused with the 208, 209 and 367 studies. Therefore, Teva's assertion that it could not reasonably determine which three studies supported the statement is belied by the NDA.

Second, and more importantly, Teva's inequitable conduct theory by itself eliminated any potential confusion Teva may have had regarding Wyeth's support for the statement. Teva's inequitable conduct theory is predicated on the assertion that the statement – "[v]enlafaxine ER showed a statistically significant improvement . . . in [three] studies" – required "that three studies *each* showed a statistically significant improvement." (Teva's Reply Br. at 7, emphasis added). According to Teva, in order to show a statistically significant improvement, a clinical study would need to compare the extended release product with the immediate release product. (*See Id.* at 8). But only one study disclosed in the NDA – the 208 study – made such a comparison. And Teva claims that that study did not show a significant improvement; rather, it "showed the *same* incidence of nausea for both formulations (45%)." (Teva Reply Br. at 8, emphasis in original). Further, Teva acknowledges that "[n]othing on the face of the [studies] themselves indicate that they provide support for any conclusion about 'statistical significance.'" (*Id.*). Consequently, because under Teva's theory of inequitable conduct none of the clinical studies disclosed in the NDA support the statement, and that should have been evident after Teva

reviewed the NDA, Teva provides no reason why it could not have asserted its inequitable conduct defense before the amendment deadline.[7]

Teva responds that because allegations of inequitable conduct are serious, and because inequitable conduct must be plead with particularity under Fed. R. Civ. P. 9, Teva acted appropriately by conducting additional discovery to confirm the factual underpinnings of its defense.[8] Although the Court agrees with Teva that no party should blithely assert a charge of inequitable conduct, nor should a party attempt to plead inequitable conduct if it is unable to do so with particularity,[9] the Court is not convinced that the Magistrate Judge erred when determining that Teva did not act diligently under the circumstances in this case. Certainly, in some cases it may be appropriate to conduct additional discovery to ascertain or develop an

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[7]Teva's argument that Wyeth did not disclose that the statement was based on a "pooled" analysis of the three studies until February 2005 is irrelevant. Regardless of what Wyeth's justification was for that statement, Teva knew before the deadline that Wyeth could not be relying on three studies that each performed a comparative analysis because the NDA, which was required to contain all relevant clinical studies, did not include three such studies. Thus, Teva did not need to know that Wyeth relied on a "pooled" analysis before raising its inequitable conduct defense.

[8]In support of this argument, Teva cites three district court cases: *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484 (D. Del. 2003); *Douglas Press, Inc. v. Int'l Gamco, Inc.*, 2004 U.S. Dist. LEXIS 7606 (N.D. Ill. May 3, 2004); *Go Med. Indus. Pty Ltd. v. C.R. Bard, Inc.*, 1995 U.S. Dist. LEXIS 22248 (N.D. Ga. July 5, 1995). Those cases, however, are inapt. First, all of the cases decided a motion for leave to amend to add an inequitable conduct defense in the first instance. None reviewed the decision of a Magistrate Judge under the deferential standard elucidated by Rule 72. Second, the last two cases, *Douglas Press* and *Go Medical*, were decided under the more permissive Rule 15(a), not under Rule 16(b). And third, although *Enzo Life Sciences* was decided in part under Rule 16, the Court expressly found that the inequitable conduct theory was based on a new set of facts discovered after the amendment cutoff date. 270 F. Supp. 2d at 489.

[9]*See Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) (stating that "inequitable conduct, while a broader concept than fraud, must be pled with particularity").

inequitable conduct defense before requesting leave to amend. However, this was not such a case. In short, Teva has failed to demonstrate that Judge Schwartz's decision was clearly erroneous or contrary to law.[10]

Conclusion

For the reasons stated above, Magistrate Judge Schwartz's Order dated May 13, 2005 is affirmed.

Dated: August 3, 2005

s/ William J. Martini
William J. Martini, U.S.D.J.

[10]Having affirmed the holding that Teva did not show good cause to modify the Pretrial Scheduling Order under Rule 16(b), the Court need not address Judge Schwartz's "observations" of undue delay, prejudice and futility under Rule 15(a).